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**This Report CONTAINS Confidential Business Information**

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**CONFIRMATION OF RECEIPT REQUESTED**

Document Control Office (7407M)  
U.S. Environmental Protection Agency  
Attn: TSCA Section 8(e) Coordinator  
Office of Pollution Prevention and Toxics  
1200 Pennsylvania Avenue, NW  
Washington, DC 20460-0001



**SUBJECT:**            **TSCA 8(e) SUBMISSION**

Dear Sir or Madam:

("            ") is submitting certain data which we believe to be reportable under TSCA 8(e). The information concerns            , an experimental sulfone insecticide compound.            is identified by IUPAC as:

The CAS number assigned for this compound is            .

                 has not imported            for R&D on behalf of            ("            ") but plans to do so in the future.

The following reports concerning            have been submitted to your agency:

- first acute oral toxicity study in rats (September 2, 2008: ~~8EHQ-08-17252~~)
- second acute oral toxicity study in rats (September 2, 2008: 8EHQ-08-17251)
- third acute oral toxicity study in rats (September 2, 2008: 8EHQ-08-17253)
- acute oral toxicity study in rats (December 18, 2010: 8EHQ-10-17828)
- one month/ one week oral toxicity in rats (July, 29, 2010: 8EHQ-10-18016)
- prenatal developmental toxicity study in rats (September 8, 2010: 8EHQ-10-18121)

- 4 day oral toxicity study in beagles (October 28, 2010: 8EHQ-10-18165)
- 4 week oral toxicity in beagles (April 15, 2011)

recently learned of new toxicological effects in two oral toxicity studies in mice. An outline of the studies follows:

**Acute oral toxicity study in mice (P1)**

was administered to 8 week old female mice (3 animals/ dose) at the concentration of 50 and 300 mg/kg.

**Performing Laboratory:**

Animals: Crlj:CD1(ICR) mice, female, 8 weeks old, 3 animals/dose  
 Body weight: 22.5-24.2 g (50 mg/kg dose), 22.4-23.8 g (300 mg/kg dose)  
 Route of administration: Oral  
 Dose levels: 50 mg/kg, 300 mg/kg  
 Dosing volume: 10 mL/kg  
 Vehicle: Corn oil  
 Pre-dosing fast: about 20 hours  
 Observation items: Clinical signs, Body weights  
 Observation period: 14 days

**RESULTS:**

LD<sub>50</sub> value (female): 50-300 mg/kg

Mortality: Two of 3 animals from the 300mg/kg group died.

No animal died in the 50 mg/kg group.

Clinical signs: None of these signs were observed in the 50 mg/kg group.

None of these signs were observed except for the findings described above.

Body Weights: No treatment-related changes were observed in survival animals..

**We judged the need for this TSCA report based on the criteria of clinical signs from the TSCA 8(e).**

**Acute oral toxicity study in mice (P2)**

was administered to 8 week old female mice (3 animals/ dose) at the concentration of 50 and 300 mg/kg.

**Performing Laboratory:**

Animals: Crlj:CD1(ICR) mice, female, 8 weeks old, 3 animals/dose  
 Body weight: 22.6-24.8 g (50 mg/kg dose), 22.5-23.6 g (300 mg/kg dose)

Route of administration: Oral  
Dose levels: 50 mg/kg, 300 mg/kg  
Dosing volume: 10 mL/kg  
Vehicle: Corn oil  
Pre-dosing fast: about 20 hours  
Observation items: Clinical signs, Body weights  
Observation period: 14 days

**RESULTS:**

LD<sub>50</sub> value (female): 50-300 mg/kg  
Mortality: All animals died in the 300mg/kg group.  
No animal died in the 50 mg/kg group.  
Clinical signs: None of these signs were observed in the 50 mg/kg group.  
None of these signs were observed except for the findings described above.  
Body Weights: No treatment-related changes were observed in survival animals

**We judged the need for this TSCA report based on the criteria of clinical signs from the TSCA 8(e).**

Substantiation of CBI Claims

We wish to substantiate       's claims that certain information in this letter be treated as Confidential Business Information ('CBI'). All information which has been deleted from the sanitized version of this letter (copy attached) should be treated as CBI. In substantiation of this CBI claim,       wishes to protect its confidential business plan for the commercial development of this compound. Disclosure of this information would harm       's efforts to commercialize this compound. Please refer to the attached letter of September 2, 2008 to Mr. Edward Gross regarding substantiation of CBI claims.

If there are any questions on this submission please feel free to contact me at (    ).

Yours sincerely,